

### **III. Remarks**

#### **A. Status of the Application**

Claims 3, 10-17, 23-40, 43, 44, 56-61, 66, 67, 70, 71, 75, 76, 86-89, 91-96, 101-103, 106-110, 112-119, 121, and 122 are currently pending. Claims 93-96, 101-103, 106-110, 112, 113, 121, and 122 were previously withdrawn from consideration as being directed to an unelected invention. Claims 41, 42, 74, and 90 are canceled by the present paper without prejudice to or disclaimer of the subject matter therein. Claim 43 has been amended to be in independent form, incorporating all of the limitations of its base claims such that the scope of claim 43 is unchanged. Claims 66, 67, and 70 have been amended to depend from and further limit claim 43. No claims are added by the present paper. Applicants appreciate the indication of allowance for claims 91, 92, and 114-119. Applicants also appreciate the indication that the above amendments overcome the rejections to claims 43, 44, 66, 67, and 70. Applicant presumes that claim 71 also overcomes the rejections as it depends from and further limits claim 70. Reconsideration of the present application in light of the following remarks is respectfully requested.

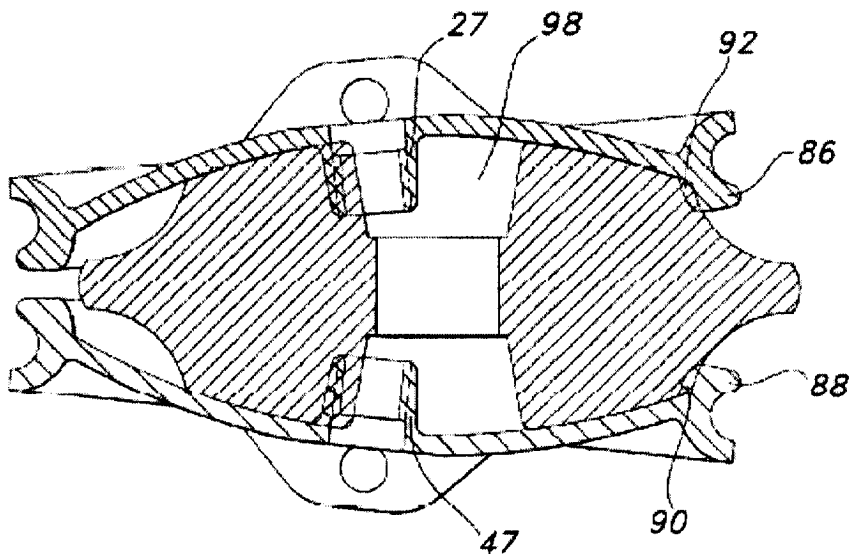
#### **B. Rejections under 35 U.S.C. § 102**

##### **1. The Buttner-Janz Patent**

The Final Office Action indicated that **claims 56-61** are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,401,269 to Buttner-Janz et al. (“the Buttner-Janz patent”). Therefore, to sustain the rejection of the claims 56-61 the Buttner-Janz patent must disclose all of the claimed elements of each claim.

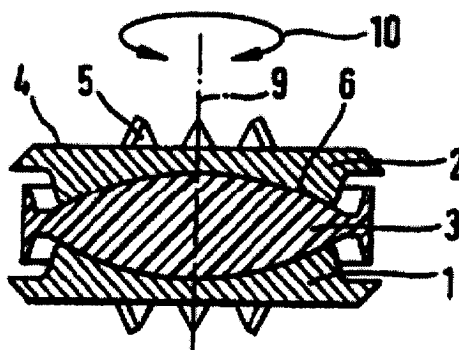
With respect to independent claim 56, as amended, the Buttner-Janz patent at least fails to disclose an implant having all of the recited features of the claim, including “wherein the central body has an upper and a lower contact surface, and wherein in the absence of a compressive load, an upper shoulder is recessed into a portion of the outer perimeter of the upper contact surface and a lower shoulder is recessed into a portion of the outer perimeter of the lower contact surface.” (emphasis added). As shown below, Fig. 8B of the present application illustrates an

exemplary embodiment of a central body having upper and lower shoulders 90 and 92 recessed into a portion of the outer perimeter of the respective contact surfaces.

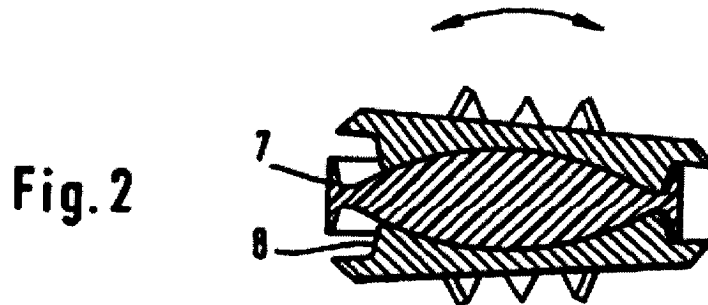


**FIG 8B**

The cited portions of the Buttner-Janz patent simply do not disclose having shoulders recessed in the upper and lower contact surfaces as recited. Rather, as shown in Figs. 1 and 2 of the Buttner-Janz patent, reproduced below, the collar 7 surrounding and defining the perimeter of the prosthesis core 3 is not recessed into the articular surfaces 6. Rather, the collar 7 projects outwardly at an increased height from the articular surfaces 6. Further, the area just inside the collar 7 having a reduced height relative to the collar cannot be considered a shoulder as recited because it is not recessed into a portion of the outer perimeter as required.



**Fig. 1**



The shoulders must be recessed into the outer perimeter or outer boundary of the device, not within the device as disclosed by the Buttner-Janz patent. It is clear that the protruding collar 7 in the Buttner-Janz patent defines the outer perimeter of the core 3. The recessed portion of the core 3 as identified by the Office Action is positioned inside the collar 7 and spaced from the outer perimeter of the core 3. Accordingly, it is clear that the core 3 of the Buttner-Janz patent does not disclose an upper shoulder recessed into a portion of the outer perimeter of the upper contact surface and a lower shoulder recessed into a portion of the outer perimeter of the lower contact surface, as recited by claim 56.

For at least this reason, the Buttner-Janz patent fails to disclose all of the limitations of independent claim 56. Claims 57 and 58 depend from and further limit claim 56. Therefore, for at least these reasons Applicants respectfully request that the §102 rejection of claims 56-58 be withdrawn.

Similar to independent claim 56, independent claim 59 requires “wherein an upper shoulder extends around a portion of the outer perimeter of the upper contact surface and a lower shoulder extends around a portion of the outer perimeter of the lower contact surface and further wherein the upper shoulder defines a ledge indented into and around the outer perimeter of the upper contact surface of the central body.” As discussed above, the Buttner-Janz patent fails to disclose such limitations. Therefore, for at least the same reasons, the Buttner-Janz patent fails to disclose an implant with all of the recited limitations of claim 59. Claims 60 and 61 depend from and further limit claim 59. Therefore, Applicants respectfully request that the §102 rejection of claims 59-61 be withdrawn.

**C. Rejections under 35 U.S.C. § 103**

**1. The Fuhrmann and Ray Patents**

**Claims 75 and 76** stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,002,576 to Fuhrmann et al. (“the Fuhrmann patent”) in view of U.S. Patent No. 6,132,465 to Ray et al. (“the Ray patent”). Applicants respectfully traverse the rejection of claims 74-76 on the grounds that these references are defective in establishing a *prima facie* case of obviousness.

As the PTO recognizes in MPEP § 2142:

... The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness...

It is submitted that a *prima facie* case of obviousness has not been factually supported with respect to each of these claims in the present case.

With respect to independent claim 75, even when combined the Fuhrmann and Ray patents fail to disclose all of the recited features of the claim, including “a central body and a lubricant encapsulated within the implant between the central body and a structure having at least one opening for the introduction of the lubricant into the structure, wherein the structure includes two shells and a sleeve extending between the shells, and the opening is included in at least one of the shells.” Rather, the opening 21 in the cover plate 3” of the Fuhrmann patent “serves to fill the interior with viscoelastic material—or, together with a similar opening, as ventilation.” Col. 4, Lines 10-12. In the Fuhrmann patent, the viscoelastic material fills a closed corrugated tube 1 to create the central spring body. Col. 2, Lines 52-67. In other words, the viscoelastic material 2 is the central body of the Fuhrmann device. Thus, the opening 21 is not for the “introduction of a lubricant into the implant between the central body and opposing shells,” as required. Rather, the opening 21 of the Fuhrmann disc is for filling the corrugated tube 1 with the viscoelastic material 2 to form the central spring body. The viscoelastic material cannot be introduced between a central body and opposing shells because the viscoelastic material is the central body. Similarly, the hydrogel core 22 of the Ray patent is positioned within the constraining jacket 24 of the prosthetic nucleus 20 and “is configured to imbibe fluids, expanding from a dehydrated

state to a hydrated state.” Col. 6, ll. 63-65. The fluids of the Ray patent are not introduced between a central body and opposing shells as required. Rather, the fluids are absorbed into the hydrogel core itself, which is the central body. Accordingly, neither the Fuhrmann patent nor the Ray patent discloses a lubricant between a central body and opposing shells as recited.

In response to these arguments, the Advisory Action again asserts that Applicant is not positively claiming these limitations. Applicants respectfully disagree. Claim 75 clearly recites “a lubricant encapsulated within the implant between the central body and a structure having at least one opening for the introduction of the lubricant into the structure.” These limitations plainly state that the lubricant is encapsulated within the implant between the central body and a structure having two shells and a sleeve extending between the shells. In contrast and as discussed above, the openings of the Fuhrmann and Ray patents do not disclose or suggest a lubricant between a central body and opposing shells as recited by claim 75.

Accordingly, for at least these reasons, even when combined the Fuhrmann and Ray patents fail to disclose all of the recited elements of claim 75. Claim 76 depends from and further limits claim 75. Accordingly, the Applicants request that the §103 rejection of claims 75 and 76 over Fuhrmann and Ray patents be withdrawn.

## **2. The Buttner-Janz, Buechel, Fuhrmann, and Ray Patents**

**Claim 3 and 10-15** stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Buttner-Janz patent in view of U.S. Patent No. 5,868,796 to Buechel et al. (“the Buechel patent”), in view of the Fuhrmann patent, in view of the Ray patent. Applicants respectfully traverse the rejection of these claims on the grounds that these references are defective in establishing a *prima facie* case of obviousness.

Claim 3 requires, “a flexible sheath extending between edges of the opposing shells, having an inner surface that, together with the inner surfaces of the rigid shells, defines a cavity containing the central body; and a liquid lubricant, which occupies at least a portion of the cavity between the central body and the opposing shells.” However, even when combined the Buttner-Janz, Buechel, Fuhrmann, and Ray patents fail to disclose such limitations. Specifically, the

references fail to disclose or suggest having a liquid lubricant within a cavity between a central body and opposing shells. In that regard, as discussed above the viscoelastic material of the Fuhrmann patent is itself the central body of the Fuhrmann disc, and is not positioned within a cavity containing a central body as required. Similarly, the fluid of the Ray patent is positioned within the hydrogel core itself and not within a cavity containing a central body. For at least this reason, even when combined the Buttner-Janz, Buechel, Fuhrmann, and Ray patents fail to teach all of the claimed elements of independent claim 3.

Further, there is no reason for combining the opening 21 of the Fuhrmann disc and fluid of the Ray patent with the devices of the Buttner-Janz and Buechel patents other than hindsight based on the present invention. Recently, the Supreme Court ruled that the “teaching, suggestion, or motivation (TSM) test” still applies, but should be used in a more “expansive and flexible” manner. *KSR Int’l. Co. v. Teleflex Inc.*, slip opinion at 14-15 (2007). The Court stated that

“A patent composed of several elements **is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* at 14-15, emphasis added.

In the present case, the Examiner has not expressed any reason why a person of ordinary skill in art would combine the opening 21 of the Fuhrmann disc with the devices of the the Buttner-Janz patent and the Buechel patent. The Final Office Action states that “it would have been obvious ... to modify the device of Buttner-Janz/Buechel/Bryan et al., as taught by Fuhrmann et al., to serve to fill or ventilate the interior of the implant. However, the devices of the Butter-Janz and Buechel patents include substantially solid core or central pieces. The central pieces of the

Buttner-Janz patent are not formed by filling a tube with viscoelastic material as in the Fuhrmann patent. Thus, one would not modify the devices of the Buttner-Janz and Bryan patents to fill the implant with a viscoelastic material to create a central body as in the Fuhrmann patent. Further, there is no indication why one would combine ventilation with the Buttner-Janz devices.

The Advisory Action states that “It is common sense that familiar items may have obvious uses beyond their [primary] purposes, and a person of ordinary skill in the art often will be able to fit the teachings of multiple patents together like a piece of a puzzle.” However, as noted above by the Supreme Court, “A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” Rather, it is “important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” No such reason has been provided in the current case. Thus, for at least this additional reason a *prima facie* case of obviousness has not been established with respect to independent claim 3.

Claims 10-15 depend from and further limit independent claim 3. Therefore, for at least the same reasons these references are defective in establishing a *prima facie* case of obviousness with respect to claims 10-15. Thus, Applicants request that the §103 rejection of claims 3 and 10-15 be withdrawn.

### **3. The Buttner-Janz, Buechel, Bryan, Fuhrmann, and Ray Patents**

**Claims 16, 17, 23-40, 43, 44, 66, 67, 70, 71, and 86-90** stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Buttner-Janz patent in view of the Buechel patent, in view of U.S. Patent No. 5,764,296 to Bryan et al. (“the Bryan patent”), in view of the Fuhrmann patent, in view of the Ray patent. Applicants respectfully traverse the rejection of claims 16, 17, 23-40, 43, 44, 66, 67, 70, 71, and 86- 90 on the grounds that these references are defective in establishing a *prima facie* case of obviousness.

**a. Claims 16 and 17**

With respect to independent claim 16, even when combined the Buttner-Janz patent, the Buechel patent, the Bryan patent, the Fuhrmann patent, and the Ray patent fail to disclose an implant having all of the recited limitations, including “a lubricant positioned between the central body and the opposing shells; wherein the closable passage is configured in a manner that permits the introduction of the lubricant into the implant between the central body and the opposing shells.” As discussed above with respect to claims 74 and 75, the opening 21 of the Fuhrmann disc is for filling the corrugated tube 1 with the viscoelastic material 2 to form the central spring body. As such, the viscoelastic material cannot be introduced between a central body and opposing shells because **the viscoelastic material is the central body**. Similarly, the hydrogel core 22 of the Ray patent is positioned within the constraining jacket 24 of the prosthetic nucleus 20 and “is configured to imbibe fluids, expanding from a dehydrated state to a hydrated state.” Col. 6, ll. 63-65. Thus, the fluids are absorbed into the hydrogel core, which is the central body. Accordingly, even when combined the Buttner-Janz, Buechel, Bryan, Fuhrmann, and Ray patents fail to disclose the recited limitations of independent claim 16.

Further, similar to the discussion above with respect to claim 3, there is no reason for combining the opening 21 of the Fuhrmann disc and fluid of the Ray patent with the devices of the Buttner-Janz, Buechel, and Bryan patents other than hindsight. The Advisory Action states that “It is common sense that familiar items may have obvious uses beyond their [primary] purposes, and a person of ordinary skill in the art often will be able to fit the teachings of multiple patents together like a piece of a puzzle.” However, as noted above by the Supreme Court, “A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” Rather, it is “important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” No such reason has been provided in the current case. Thus, for at least this additional reason a *prima facie* case of obviousness has not been established with respect to independent claim 16.

For at least these reasons, a *prima facie* case of obviousness has not been established with



respect to claim 16. Claim 17 depends from and further limits claim 16. Therefore, Applicants respectfully request that the §103 rejection of claims 16 and 17 be withdrawn.

**b. Claims 23-40**

With respect to independent claim 23, even when combined the Buttner-Janz patent, the Buechel patent, the Bryan patent, the Fuhrmann patent, and the Ray patent fail to disclose an implant having all of the recited limitations, including “an elastic sheath disposed between the upper and lower shells and external to the central body, comprising an inner surface, an outer surface, an upper edge attached to the upper shell, and a lower edge attached to the lower shell; wherein the inner surface of the sheath and the inner surfaces of the shells define an enclosed cavity; and a lubricant disposed within the enclosed cavity surrounding the central body.” Even when combined these references fail to disclose an implant with a lubricant disposed within an enclosed cavity surrounding the central body, the cavity defined by the inner surface of a sheath and the inner surfaces of the shells. As discussed above, the viscoelastic material of the Fuhrmann patent is the central body of the Fuhrmann disc and the fluid of the Ray patent is positioned within the hydrogel core. Also, as discussed above with respect to claim 16, no reason—other than hindsight based on the present invention—has been expressed why a person of ordinary skill in the art would combine the references as suggested. For at least these reasons a *prima facie* case of obviousness has not been established with respect to independent claim 23. Claims 24-40 depend from and further limit claim 23. Therefore, for at least the same reasons these references are defective in establishing a *prima facie* case of obviousness with respect to claims 24-40.

Thus, Applicants request that the §103 rejection of claims 23-40 over the Buttner-Janz, Buechel, Bryan, Fuhrmann, and Ray patents be withdrawn.

**c. Claims 43, 44, 66, 67, 70, and 71**

As noted above, Applicants appreciate the indication that these claims overcome the previous rejections.

**d. Claims 86 and 87**

With respect to independent claim 86, even when combined the Buttner-Janz patent, the Buechel patent, the Bryan patent, the Fuhrmann patent, and the Ray patent fail to disclose an implant having all of the recited limitations, including “two shells interconnected by a sleeve to form a cavity therein, and a central body having at least one indentation therein positioned within the cavity, a lubricant within the cavity between the central body and the two shells; wherein at least one of the shells includes an opening to allow introduction of the lubricant into the cavity.” These references fail to disclose an implant with an opening to allow the introduction of a lubricant into a cavity defined by two shells and a sleeve with a central body positioned in the cavity, as recited. Again, the viscoelastic material of the Fuhrmann patent is the central body of the Fuhrmann disc and the liquids of the Ray patent are absorbed by the central body. Further, as discussed above, no reason—other than hindsight based on the present invention—has been expressed why a person of ordinary skill in the art would combine the references as suggested. Accordingly, for at least these reasons a *prima facie* case of obviousness has not been established with respect to independent claim 86. Claim 87 depends from and further limits claim 86. Thus, Applicants respectfully request that the §103 rejection of claims 86 and 87 be withdrawn.

**e. Claims 88 and 89**

With respect to independent claim 88, even when combined the Buttner-Janz, Buechel, Bryan, Fuhrmann, and Ray patents fail to disclose an implant having all of the recited features, including “a lubricant within the cavity between the central body and the two shells; wherein at least one of the shells includes an opening to allow introduction of the lubricant into the cavity, wherein the opening is sealed with a plug tool having a handle and a detachable integral plug associated therewith after introduction of the lubricant into the cavity.” As discussed above, neither the Fuhrmann or Ray patents disclose a lubricant within the cavity between the central body and two shells and no reason—other than hindsight—has been provided

for combining the references as suggested. Further, none of the cited references appear to disclose “wherein the opening is sealed with a plug tool having a handle and a detachable integral plug associated therewith after introduction of the lubricant into the cavity” as required. For at least these reasons, a *prima facie* case of obviousness has not been established with respect to claim 86. Claim 89 depends from and further limits claim 88. In that regard, claim 89 also requires “wherein the plug detaches from the tool when a predetermined torque has been reached during insertion of the plug into the opening.” The cited references do not appear to disclose such limitations. Therefore, Applicants respectfully request that the §103 rejection of claims 88 and 89 be withdrawn.

#### IV. Conclusion

It is believed that all matters set forth in the Office Action have been addressed and that all of the pending claims under consideration are in condition for allowance. Should the Examiner deem that an interview with Applicants' undersigned attorney would expedite consideration, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.

Respectfully submitted,



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